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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,385	01/03/2001	Michael W. Heartlein	10278-025004	2793

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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/753,385

Applicant(s)

HEARTLEIN ET AL.

Examiner

Claire M. Kaufman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-51 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43,45,46 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 43-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> | 6) <input type="checkbox"/> Other: |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 44 and 47-50 and the portions of claims 45, 46 and 51 not drawn to GAG or transferring receptor.

DETAILED ACTION

The preliminary amendment filed 3/26/01 has been entered.

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: i) endogenous substance: lipoprotein, bile salt, acetylated LDL, glycosaminoclycan, glycolipid, hormone, cytokine, glucose, lipid, immunoglobulin; ii) cell surface receptor: transferrin receptor, serum albumin receptor, asialoglycoprotein receptor, CD4, immunoglobulin Fc receptor, α -fetoprotein receptor, LRP receptor, LDL receptor, mannose receptor.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 43 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Leda Travenos on June 18, 2003, a provisional election was made with traverse to prosecute the invention wherein the species of endogenous substance is glycosaminoglycan (GAG) and the cell surface receptor is transferrin receptor,

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corresponding to claims 43, 45, 46 and 51. Affirmation of this election must be made by applicant in replying to this Office action. Claims 44 and 47-50 and the portions of claims 45, 46 and 51 not drawn to GAG or transferring receptor are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The disclosure is objected to because of the following informalities: p. 62, line 21, "the" should be replaced with --that--, and in Table 2 on p. 68, about lines 5-7, the small print in column 1 below "None" is illegible.

Appropriate correction is required.

Claim Objections

Claims 45, 46 and 51 are objected to for reciting non-elected species.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43 and dependent claims 45, 46 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what substances are included in the meaning of "endogenous substance" (line 1 of claim 43). It is not clear from the specification if this excludes or includes foreign substances (*e.g.*, HIV) found in the extracellular fluid (paragraph bridging pages 4-5). Stedman's Medical Dictionary 27th Edition (online) defines endogenous as "Originating or produced within

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the organism or one of its parts.” Therefore, for HIV, because once infected it produced within the body, it is endogenous and one could consider that it is no longer foreign.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 43 and 51 are rejected under 35 U.S.C. 102(a) as being anticipated by Shin et al. (AZ, PNAS, 92:2820, 1995).

Shin et al. teach a method of lowering the amount of in an endogenous substance in an extracellular fluid using a transferrin-IgG3 antibody fusion protein that binds transferrin (Tf) receptors and is transported across the blood brain barrier of rats, most probably by binding to receptors on capillary endothelial cells and being transported into the cells (p. 2822, col. 2, 2nd full ¶, Fig. 5, and p. 2823, col. 2, 1st full ¶). Also the FcγRI binding ability of the antibody portion, IgG3, remained intact after transport (p. 2822, col. 2, 1st full paragraph). The transferrin portion was derived from human Tf cDNA and the antibody portion was from a human or humanized IgG3 heavy chain gene.

Claims 43 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Capon et al. (AV, Nature, 337(9):525, 1989).

Capon et al. teaches a CD4-IgG chimeric protein (legend of Fig. 1, end of first paragraph) which binds gp120 and an Fc receptor. It was shown that the IgG portion of the chimeric protein bound Fc Receptor, increased half-life of the chimeric protein and its transport into a cell (e.g. p. 527 and p. 530, col. 2, first full paragraph). Also taught is administration of the chimeric protein into rabbits (p. 527, first paragraph, and Table 1) which would, absent evidence to the contrary, lower the amount of HIV in an extracellular fluid of the rabbit.

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Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. LaFont et al. (Dev. 114(1): 17-29 (1992)), discusses the desirable activities of GAGs, such as their ability to bind, concentrate and eventually internalize several basic growth factors (p. 17, col. 2, beginning of first full paragraph) and to promote neurite outgrowth (p. 24, middle to first full paragraph). Nevertheless, the Examiner believes that the instant invention restricted to the elected species of chimeric protein comprised of a GAG-binding domain coupled to transferrin would not have been obvious in view of the prior art, and it would require improper hindsight to say otherwise.

Conclusion

Claims 45, 46 and 51 would be allowable if restricted to the elected species and rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

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Claire M. Kaufman, Ph.D.

A handwritten signature in cursive script, appearing to read "Claire M. Kaufman", written in black ink.

Patent Examiner, Art Unit 1646

June 23, 2003